



Food and Drug Administration  
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October 22, 2014

Zimmer, Incorporated  
Mr. Stephen H. McKelvey, MA, RAC  
Senior Project Manager, Trauma Regulatory Affairs  
P.O. Box 708  
Warsaw, Indiana 46581-0708

Re: K142579

Trade/Device Name: *Zimmer®* Periarticular Plating System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: HRS, HWC  
Dated: September 12, 2014  
Received: September 15, 2014

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Lori A. Wiggins -S**

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

## Indications for Use

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

510(k) Number (if known)

K142579

Device Name

Zimmer Periarticular Plating System

Indications for Use (Describe)

Periarticular Plating System Small Distal Volar Radial Radius and Small Distal Volar Ulnar Radius plates are indicated for temporary internal fixation and stabilization of fractures and osteotomies of the volar aspect of the distal radius, including associated carpal fusions.

Periarticular Plating System Calcaneal plates are indicated for complex extra-articular and intra-articular fractures and osteotomies of the calcaneus.

Periarticular Plating System screws are temporary internal fixation devices designed to stabilize fractures during the normal healing process.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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### **510(k) Summary**

**Sponsor:** Zimmer, Inc.  
P.O. Box 708  
Warsaw, IN 46581-0708

**Contact Person:** Stephen H. McKelvey  
Senior Project Manager, Trauma Regulatory Affairs  
Telephone: (574) 372-4944  
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**Date:** September 12, 2014

**Trade Name:** *Zimmer*<sup>®</sup> Periarticular Plating System

**Common Name:** Periarticular Non-locking Plates and Screws

**Classification Names and References:** Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR 888.3030 (HRS);  
Smooth or Threaded Metallic Bone Fixation Fastener 21 CFR 888.3040 (HWC)

**Classification Panel:** Orthopedics/87

**Predicate Device(s):** *Zimmer* Periarticular Plating System Screws (K111447)  
Synthes Distal Radius Plate System (K982732)  
Synthes Calcaneal Plate (K020401)

**Purpose and Device Description:** The *Zimmer* Periarticular Plating System consists of temporary implants (plates and screws) and instrumentation for the management of periarticular bone fractures through interfragmentary compression and bone plating. Bone screws are provided for use with or without bone plates for fractures. This submission covers non-sterile versions of previously cleared sterile Zimmer Periarticular Plating System screws and various sizes of the following sterile plates: Distal Volar Radial Radius, Distal Volar Ulnar Radius, Lateral Calcaneal.

**Intended Use:**

Small Distal Volar Radial Radius and Small Distal Volar Ulnar Radius plates are indicated for temporary internal fixation and stabilization of fractures and osteotomies of the volar aspect of the distal radius, including associated carpal fusions. Calcaneal plates are indicated for complex extra-articular and intra-articular fractures and osteotomies of the calcaneus. Screws are temporary internal fixation devices designed to stabilize fractures during the normal healing process.

**Comparison to Predicate Device:**

The *Zimmer* Periarticular Plating System plates and screws covered by this submission are substantially equivalent to the predicate devices, in that they have the same intended use, function, and fundamental scientific technology. The differences between the subject and predicate devices do not raise new issues of safety or effectiveness.

**Performance Data (Nonclinical and/or Clinical):**

Non-Clinical Performance and Conclusions:

- **Shelf Life** - Accelerated aging testing conducted shows that the sterile devices included in this submission have a shelf life of 10 years.
- **Biocompatibility** – Biocompatibility testing of the subject devices was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.
- **Performance Testing** – Engineering analysis demonstrates the devices are safe and effective and substantially equivalent to the predicate devices.

Conclusions: The non-clinical performance data presented in this submission show the subject devices will perform in a substantially equivalent manner to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices to show substantial equivalence.